

Product: Sulpiride  
Batch number: 24041  
Batch size: 564.0 Kg  
Analysis number: PF198/24  
Quality standard: Eur. Ph. Current Edition



CAS number: 15676-16-1  
ICROM code: PF-0001  
Manufacturing date: September 2024  
Retest date: September 2029

PARAMETERS	RESULTS	SPECIFICATIONS
<i>Characters:</i>		
Appearance	Complies	White or almost white crystalline powder
<i>Identification:</i>		
IR	Positive	Positive
Melting point	179°C	177°C to 181°C
<i>Tests:</i>		
Solution (10% in 12% acetic acid)	Clear, < Ref. Sol. Y <sub>6</sub>	Clear, ≤ Ref. Sol. Y <sub>6</sub>
Sulphated ash	< 0.1%	≤ 0.1%
Loss on drying	< 0.1%	≤ 0.5%
Chlorides	< 100 ppm	≤ 100 ppm
Iron	< 10 ppm	≤ 10 ppm
Impurity A (TLC)	< 0.1%	≤ 0.1%
<i>Related substances (HPLC):</i>		
any impurity	< 0.05%	≤ 0.10%
total	< 0.05%	≤ 0.3%
Methanol (GC)	< LOQ (94 ppm)	≤ 500 ppm
<i>Assay:</i>		
Potentiometric (dried substance)	100.0%	98.5% to 101.0%

Date: October 24, 2024

Chiara Ghinami  
Quality Control Manager

Quality Assurance Revision: Francesca Ambrosio 24.10.24

I declare that the product is manufactured in accordance with the guidelines on Good Manufacturing Practice for Active Substances

Qualified Person Release:

 24/10/2024